PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
John W. Dohner, et al.

Serial No.: 10/658,274

Filed: September 8, 2003

For: IMPROVED METHOD FOR PREVENTING CRYSTAL FORMATION IN A DISPERSION OF A LIQUID IN A MATRIX

Examiner: Sharon Lee Howard

Group Art Unit: 1615

Attorney Docket No.: ARC 2363 N3

Commissioner for Patents
Mail Stop Non-fee Amendment
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION under Rule 1.131

Sir:

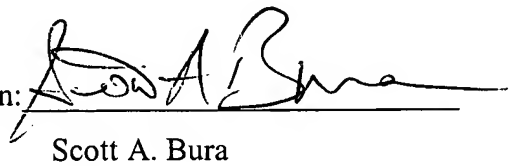
I, Scott A. Bura, hereby declare that:

1. I am a citizen of the United States and I reside in Davis, California.
2. I received my undergraduate degree in Chemical Engineering from University of California at Berkeley.
3. I have been employed at ALZA Corporation since 1990 and my current title is Project Manager, Engineering Administration. I have been involved in transdermal drug delivery development projects since 1993.
4. I am a coinventor of the above-identified patent application and I am familiar with the research and development work done related to said patent application.

5. My coinventors and I invented the invention of the above-identified patent application before April 21, 1995. Before April 21, 1995, we discovered melting scopolamine crystals (including anhydrous scopolamine crystals) on a film and annealing for producing a laminate substantially free of such crystals.
6. A copy of a record of an e-mail message that was sent by a Jim Osborne and forwarded to me on July 5, 1994 is submitted herewith as evidence to support this Declaration. The email message reported that the melting of scopolamine anhydrous crystals was confirmed by Joan Huey-Dow. It also discussed annealing.
7. My coinventors and I exercised due diligence regarding this invention from April 21, 1995 to the time of the original filing of a patent application from which the above identified patent application stems.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 or Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 22Nov04

Sign: 

Scott A. Bura

(33] From: Marc Ekelund at ALZA-V 7/5/94 2:37PM (4142 bytes: 1 ln)
To: Scott Bura at ALZA-NR, John Dohner at ALZA-M
Subject: Re[4]: Scop crystal investigation samples
---------- Forwarded ----------
From: Jim Osborne at ALZA-BCQ 7/5/94 12:44PM (3909 bytes: 1 ln)
To: Kraig Evans at ALZA-V, Marc Ekelund at ALZA-V
cc: Joan-Huey Dow at ALZA-NR
Subject: Re[4]: Scop crystal investigation samples
---------- Message Contents ----------
Joan has confirmed the melting point reported by McCrone (about 69C), by two techniques, microscopy and DSC. Also, samples placed in a humid environment for four days changed slightly in appearance, and the melting point apparently dropped to about 59C after four days hydration, which is consistent with the Scop hydrate crystals we had in systems a few years ago. There will be a few other tests to confirm the identity of the crystals, including consultation with Myron to see if there are analytical techniques that will directly identify, but it appears the crystals in the system are anhydrous Scop crystals. The mystery for me is why are we now getting anhydrous crystals in the system rather than hydrate crystals as before.

We do not see any kinetic limitation to melting the crystals. The crystals melt as soon as they reach the melting temperature and not before. Are you planning to try to deal with this crystal problem the same as before, by heating the laminate above the melting temperature to eliminate the crystal seeds. If so, then the observations on melting kinetics say the annealing time is not important as long as you get the entire laminate above the melting temp (69C). Another way you could consider is to convert the crystals to hydrate form prior to annealing, and then anneal the same as the current annealing protocol. I am not sure how you can practically perform that conversion to hydrate. Jim

Reply Separator